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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,267	10/31/2001	Lakshmi Rambhatla	093/004P	1874
22869	7590	09/19/2006	EXAMINER	
GERON CORPORATION 230 CONSTITUTION DRIVE MENLO PARK, CA 94025			TON, THAIAN N	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/001,267

Applicant(s)

RAMBHATLA ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 41-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

Applicants' Amendment and Remarks, filed 7/11/06, has been entered. Claims 41-50 are pending and under current examination.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 21-28 of copending Application No. 10/087,142. This rejection is *maintained* for reasons of record advanced in the Office action, mailed 11/23/05.

*Applicants Arguments.* Applicants' traverse this rejection because they argue that the '142 application currently does not contain any claims directed to the use of butyrate in the differentiation process, and that, in fact, the '142 application only

has one claim pending, and thus, any reasoning applied in the earlier Office Actions is no longer applicable and the double patenting rejection should be withdrawn. See page 5 of the Response.

*Response to Arguments.* These arguments have been fully considered, but are not persuasive. The '142 claims have now been allowed. The allowed claims are directed to methods for obtaining hepatocyte lineage cells by differentiation of pPS cells in a growth environment that comprises butyrate or a butyrate analog. The instant claims are directed to culturing pPS cells in a medium that recites butyrate and specific analogs of butyrate. Thus, although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of differentiating pPS cells into differentiated cells that have the morphological features of hepatocytes. The instant claims are directed to methods of producing hepatocyte lineage cells from pPS cells, comprising culturing the pPS cells in a medium comprising a hepatocyte lineage differentiation agent selected from sodium butyrate, n-butyric acid, trichostatin A, propionic acid, isobutyric acid, and isoavaleric acid. Further embodiments recite that the initiation of differentiation of cells is initiated in a medium containing DMSO, dimethylacetamide, hexamethylene bisacetamide, or another polymethylene bisacetamide (claim 45). The '142 claims are directed to methods for producing hepatocytes lineage cells by culturing the pPS cells in a growth environment that comprises butyrate or an analog of butyrate and one or more hepatocytes maturation factors that are either an organic solvent selected from DMSO, DMA, hexamethylene bisacetamide, and other polymethylene bisacetamides; or b) a cytokine or hormone selected from glucocorticoids, EGF, insulin, TGF- $\alpha$ , TGF- $\beta$ , FGF, HGF, IL-1, IL-6, IGF-II and HBGF-1.

The instant claims differ from the '142 claims in that the instant claims recite specific analogs of butyrate, and the '142 claims recite specific hepatocyte maturation factors. However, using the '142 specification as a dictionary to define

the growth environment to differentiate the pPS cells; see, for example, Table 12, Protocol #2, clearly shows using the variously recited solvents (for example, DMSO), with butyrate, to produce hepatic lineage cells. Both sets of claims provide for the production of hepatocyte lineage cells. Accordingly, the instant claims are rendered obvious in view to the '142 claims, and this rejection is found to be proper and is maintained. Because the '142 claims are now allowed, this rejection is no longer provisional.

*Claim Rejections - 35 USC § 112*

The prior rejection of claims 41-50 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.

Applicants' arguments with regard to the requirement for a single concentration of the hepatocyte lineage differentiation agent is found to be persuasive in view of the working examples, which show that 2.5 mM of butyrate, as well as 100nM concentrations of trichostatin A produce hepatocyte lineage cells.

*Conclusion*

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Ram Shukla, SPE of Art Unit 1632, at (571) 272-0735. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*tnt*  
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Patent Examiner  
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**SUPERVISORY PATENT EXAMINER**